NOAA DIVING PROGRAM
MINIMUM MANUFACTURING AND PERFORMANCE REQUIREMENTS FOR CLOSED CIRCUIT MIXED GAS REBREATHERS

BACKGROUND INFORMATION

In the late 1990's, the NOAA Diving Program (NDP) received several requests from NOAA personnel to undergo training on commercial-off-the-shelf (COTS) rebreathers. The requests were reviewed by the NOAA Diving Safety Board and several of the requests were approved and the training was conducted by commercial vendors.

Upon further investigation into the various COTS units being utilized for training, it was discovered that very few had undergone any type of testing other than that conducted by the manufacturers' themselves. The NDP decided to evoke a moratorium on further training in rebreathers until appropriate testing was completed and the NDP was satisfied that the units were safe for use by NOAA personnel. The moratorium went into effect in 2001 and at the same time the NDP initiated a T&E program to thoroughly investigate COTS rebreathers for potential use by NOAA personnel.

The first step in the T&E program was to conduct a survey of all NOAA divers to determine what features and characteristics they most desired in rebreathers. The results indicated that efforts should be focused on closed-circuit, mixed-gas rebreathers – (CCR). Utilizing the information from the survey, the NDP compared the list of desired features and characteristics with those of commercially available units. Several units matched the requirements – however, none of them had been third-party tested to the satisfaction of the NDP.

In an effort to help advance the program, the NDP contracted the US Navy Experimental Diving Unit (NEDU), in Panama City, FL to perform manned and unmanned tests of two COTS CCRs not previously tested by NEDU. However, before testing could be started it was necessary to determine what tests needed to be performed and what criteria would be used to determine acceptable results for each test. A test protocol was developed with assistance from several experts in the field of rebreathers and presented to NEDU. The tests, a subset of the tests used by NEDU, were conducted and the results summarized in two written reports.

Following testing of the units, the next step was to develop minimum manufacturing and performance requirements for closed circuit mixed gas rebreathers. It was at this point that the NOAA Undersea Research Program (NURP) joined forces with the NDP to help co-develop these minimum requirements. For the last year a team including NOAA personnel, rebreather users, University Diving Safety Officers, and outside consultants, has been working to produce these requirements. A similar, yet more comprehensive, document was published by the European Union in 2003, and its requirements are generally compatible with the NOAA requirements.

As stated in the introduction to the document, "the purpose is to establish minimum qualification criteria by which closed circuit mixed gas rebreathers (CCRs) will be evaluated for potential use by NOAA, NOAA sponsored, or otherwise NOAA authorized, personnel. The criteria outlined in the document were selected to provide NOAA management with a fair assurance that the equipment will not endanger the diver, will not limit his ability to perform the work, and will do what the manufacturer claims it will do. The goal is to ensure that NOAA authorized CCRs are reliable, operator friendly, and meet or exceed reasonable performance standards."

A draft of this document was posted on the NDP website in November 2004 for dissemination to and comments from the general public. On 1 January 2005 all comments received were reviewed and several suggestions were incorporated in the final document which was officially adopted on 1 March 2005. Effective immediately, all CCRs will have to comply with the requirements outlined in this document in order to be considered for use by NOAA personnel and others diving under the auspices of the NOAA Diving Program. Manufacturers are encouraged to submit evidence of compliance with this document for review by the NOAA Diving Center.

NATIONAL OCEANIC AND ATMOSPHERIC ADMINISTRATION
MINIMUM MANUFACTURING AND PERFORMANCE REQUIREMENTS
FOR
CLOSED CIRCUIT MIXED GAS REBREATHERS
REVISION 1

INTRODUCTION

The purpose of this document is to establish minimum qualification criteria by which closed circuit mixed gas rebreathers (CCRs) will be evaluated for potential use by NOAA, NOAA sponsored, or otherwise NOAA authorized, personnel. For the purpose of this standard, the term closed circuit mixed gas rebreather (CCR) refers to electronically-controlled, self-contained underwater breathing apparatus that "recycles" each breath a diver takes, cleanses the carbon dioxide from it, and replenishes the oxygen. The gas is thus recirculated within the apparatus, and the inspired partial pressure of oxygen remains within acceptable physiological limits.

These criteria were selected to provide NOAA management with a fair assurance that the equipment will not endanger the diver, will not limit his ability to perform the work, and will do what the manufacturer claims it will do. The goal is to ensure that NOAA authorized CCRs are reliable, operator friendly, and meet or exceed reasonable performance standards.

These criteria apply to commercially available off-the-shelf-equipment and are not a design standard. This document only includes a few key items and it is expected that the manufacturer’s quality control program will ensure that best commercial practices are followed in the design, manufacture, and testing of the CCR and replacement parts. These criteria are not driven by a particular dive profile. It is the responsibility of the purchaser and user to match their needs with the capabilities of the rebreather.

Fulfillment of these requirements does not imply endorsement or intent to purchase by NOAA.

OVERVIEW OF CHANGES

This document contains two (2) changes to the original specifications required for unmanned testing. Change #1 specifies a breathing frequency (breaths per minute) required for testing breathing resistance (see A.2.3). Change #2 corrects the ventilation rate used to test the oxygen set point control from 50 lpm to 40 lpm (see A.1.5).

A vertical line in the left margin will mark those sections of text containing changes. This document supersedes all previous versions and is effective as of 21 April 2005.

QUALIFICATION CRITERIA

1. MANUFACTURED AND TESTED TO AN ACCEPTABLE QUALITY CONTROL PROGRAM.

The CCR must be manufactured according to an acceptable Quality Assurance and Quality Control (QA/QC) system. The industry standard for a QA/QC program is ISO 9001 (appropriate year) specifically for the manufacture of CCRs. Companies can submit their own QA/QC) program for consideration, but they must demonstrate to NOAA's satisfaction, as documented by third party certification, that it contains the essential elements of an ISO 9001 registered program. The manufacturer shall support the apparatus design by providing documentation of a failure mode effect and criticality analysis (FMECA) and qualification/acceptance testing for all components, including software, supplied with the unit. The achievement of ISO 9001 certification would also imply a strong quality management system.

2. CAPABILITIES, COMPONENTS, AND PERFORMANCE REQUIREMENTS

These requirements are designed to qualify candidate CCRs and to provide users and operational units the information they need to select an appropriate CCR and safely conduct training and operations. The CCR must include the specified capabilities / components and meet the listed performance requirements. The documentation for each CCR submitted for approval must include a description of how and when each requirement in this standard was satisfied, and the certification reports from NOAA approved independent third party witnesses.

2.1 CAPABILITIES / COMPONENTS

2.1.1 Diluent Gas System

Volume as specified by the manufacturer. Must be capable of using air, nitrogen-oxygen, helium-oxygen, or nitrogen-helium-oxygen gases. Automatic and manual addition valves are required. The diver must be able to reach and easily operate the manual addition valve at all times.

2.1.2 Gas Cylinders

Must be approved by the DOT, another government agency, or a NOAA approved certifying authority. Each cylinder shall be fitted with a pressure indicator. If this is an analog gauge it does not require a back up. If the primary display is electronic, then a back up is required. The diver must be able to reach and easily operate the cylinder valves at all times.

2.1.3 Oxygen Control System

The CCR shall contain an electronic oxygen control system that uses a minimum of three oxygen sensors providing the control system with independent voting logic. The minimum set point shall be no lower than 0.5 ATM and the maximum set point shall be no higher than 1.5 ATM. The CCR shall include an audible and/or visible warning system for High and Low PO_2 conditions. A manual oxygen addition valve is required and the diver must be able to reach and easily operate the manual addition valve at all times.

2.1.4 Oxygen Compatibility

All components that come into contact with high-pressure gas with an oxygen content greater than 40% (by volume) shall be designed and manufactured for use with high-pressure oxygen. The manufacturer shall supply the components cleaned for oxygen service using the instructions in the NOAA Diving manual or an equivalent industry or military standard. High pressure is the pressure inside the pressure vessel(s) and between the pressure vessel(s) and any pressure reducer (including the pressure reducer).

2.1.5 System Power on/off switch

A power on/off switch shall be provided, and the switch must be protected from being accidentally turned off.

2.1.6 Visual Display

Must have two separate and independent means of displaying oxygen partial pressure for each sensor.

2.1.7 Battery Condition

The CCR shall include an audible or visual low battery alarm.

2.2 PERFORMANCE REQUIREMENTS

2.2.1 Breathing loop

The breathing loop must be free of any materials or components that could provide a source of ignition or that may off-gas noxious or hazardous gases or otherwise are potentially harmful for human life support, e.g. batteries or PVC coatings. (See Required Testing Appendix A.1.4 Breathing Loop Gas Sample) It is understood that the CO_2 absorbent is potentially harmful if the canister is flooded.

2.2.2 Breathing resistance

The breathing resistance shall be in accordance with specifications outlined in Appendix A.1.3 and A.2.1 of this document.

2.2.3 Carbon Dioxide Removal

The endurance of the CO_2 removal canister will be determined by the testing specified in required Testing Appendix A.1.6 CO_2 Removal Canister Duration.

2.2.4 Hydrostatic Load

Not to exceed -25 mbar or +23 mbar (See Required Testing Appendix A.1.2 Hydrostatic Load).

2.2.5 Oxygen Control System

Control at set points within +/- 0.05 ATM (See Required Testing Appendix A.1.5 Oxygen Set Point Control and A.2.2. Oxygen Control)

2.2.6 System Weight

The system weight shall be as measured in Required Testing Appendix A.1.1 System Weight.

Appendix A: <u>REQUIRED TESTING</u>

A.1: UNMANNED TESTS

The system must meet or exceed the tests outlined below, or their equivalent, which are to be conducted and certified by an independent, third party. The unmanned tests described in these qualification criteria are taken directly from the U.S. Navy unmanned test methods and performance goals (ref. US Navy Experimental Diving Unit Technical manual No. 01-94, June 1994). Only NOAA approved laboratories will be acceptable for qualifying to this standard. Currently approved laboratories include; the U.S. Navy experimental Diving Unit, the Defence Research and Development Canada, and the Defense Evaluation and Research Agency (Great Britain). Laboratories qualified to perform CE - Mark testing will also be acceptable. Other laboratories will be considered on a case-by-case basis.

A.1.1 System Weight

The CCR dry weight in pounds will be recorded with the CCR in dive-ready condition. Dive-ready is defined as that of a fully assembled rig with the CO_2 absorbent canister filled with the appropriate type and amount of absorbent material, and gas cylinders filled with the appropriate gas to maximum operating pressure. Trim counter weights and /or weight belts not directly integrated into the CCR are not included in weight measurements. CCR weight, CO_2 absorbent material weight, and gas cylinder contents and pressures are to be recorded.

Performance Requirement: Information only.

A.1.2 Hydrostatic Load

The hydrostatic load of the CCR is the pressure that exists in a diver's lungs in the absence of flow, a pressure that directly affects the diver's level of dyspnea (sensation of breathlessness). Hydrostatic load will vary depending upon the position of the diver within the water column. The CCR will be placed on a mannequin, air added to fill half the breathing loop's compliant volume, and rotated 360 degrees in 90 degree increments, starting from the upright position. The hydrostatic load will be mouth pressure referenced to the mannequin's supersternal notch. Because these are static measurements, they will only be performed once. The data will be reported in a table of position and hydrostatic load reported as + or - mbar.

Performance requirement: Load must not exceed –25 mbar or +23 mbar. However, users should note that any values that exceed -10 mbar or +20 mbar might affect their comfort in the water.

A.1.3 Breathing Resistance

Breathing resistance is defined as the volume-averaged pressure measured as resistive effort and peak-to-peak mouth pressure. This specification is based on the normal working conditions anticipated for civilian scientific divers while wearing CCRs and will be evaluated at the Respiratory Minute Volumes (RMV) of 22.5, 40, and 62.5 liters per minute (L/min). The CCR will be set up in a horizontal attitude in ambient water. Ten pressure-volume (P-V) loops will be performed for each RMV at each depth. Peak inhalation and exhalation pressures (kPa) will be measured at each depth and RMV. The area under the curve will be reported as kPa or J/L for each P-V loop generated at each depth and RMV. A graphical representation of all 10 loops for each depth and RMV will also be produced. Breathing resistance (J/L) measured for each depth and RMV will be graphed. Using the acquired P-V loops, peak inhalation and exhalation pressures will be determined at each depth and RMV.

With air as the diluent gas tests will be performed from the surface (0 fsw/msw) to 165 fsw (50.3 msw) in 33 fsw (10 msw) increments.

Performance Requirements: Breathing resistance values must not exceed the following:

Tidal Volume (L)	*Breathing Frequency (B/min)*	Ventilation Rate (L/min)	Maximum WOB (J/L)
1.5	*15*	22.5	<1.18
2	*20*	40	<1.70
2.5	*25*	62.5	<2.38

A.1.4 Breathing Loop Gas Sample

Gas sample analysis will be performed on the CCR following the completion of a breathing resistance test at 130 fsw (39.6 msw) and during the decompression from that test. When the chamber reaches 60 fsw (18.3 msw) the ascent is stopped. The surface end of the inspired gas sample line is shifted to a cleaned and evacuated gas analysis cylinder. A sample of the CCR breathing loop is obtained and sent to a laboratory for trace contaminant analysis.

The sample will be analyzed for the following constituents:

Constituent	CAS No.	Limit (ppm)
Carbon Monoxide	630-08-0	10
Total hydrocarbons	NA	25
Total halogenated hydrocarbons	NA	10
Benzene	71-43-2	0.1
Methanol	67-56-1	7
1,1,1–Trichloroethane	71-55-6	2.5
Vinylidene chloride	75-35-4	0.15
Trichloroethylene	79-01-6	0.1
1,2-dichloroethylene	540-59-0	0.1
Xylene	1350-20-7	10
Formaldehyde	50-00-0	0.1
Ammonia	7664-41-7	10

Experience has found potential gas contaminants within breathing gas systems. If any hydrocarbons are detected within the gas sample, the gas must be analyzed for any other potential contaminant in addition to those specifically targeted.

Performance Requirement: All trace gases below allowable limits for life support breathing gas.

A.1.5 Oxygen Set Point Control

This test measures the ability of the system to maintain the oxygen partial pressure of the breathing gas at preset levels during a dive. For electronically controlled CCRs oxygen control should be independent of depth. However, depending upon the method the CCR uses to inject oxygen into the breathing loop, the oxygen level may exceed safe limits during compression. This can be compensated for during operations by slowing or temporarily halting the compression.

The CCR oxygen control is evaluated with air as the diluent at 60 fsw (18.3 msw) and 300 fsw (91.4 msw). The number of set points tested will vary with the capability of each system. If high and low set points are provided, both will be tested. For a CCR with multiple set points the low set point, a mid range set point, and the high set point will be evaluated. The oxygen consumption of an exercising diver will be simulated using oxygen consumption rates of 1.0, 1.5 and 2.5 standard liters per minute (slpm) for the respective ventilation rates of 22.5, *40*, and 62.5 L/min.

The CCR is pressurized to a depth of 60 fsw (18.3 msw) at a rate of 60 feet per minute (18.3 mpm). After the oxygen control is stabilized at 60 fsw (18.3 msw), the CCR is tested for 30 minutes. The CCR is then pressurized to 300 fsw (91.4 msw) at a rate of 60 fpm (18.3 mpm). After oxygen control is stabilized the CCR is tested for 30 minutes then depressurized at 30 fpm (9.1 mpm) to a simulated decompression stop at 30 fsw (9.1 msw). After the oxygen control is stabilized at 30 fsw (9.1 msw), the CCR is depressurized to the surface. A minimum of five runs per test condition will be performed. Data of PO_2 vs. time will be graphically represented. After the CCR is stabilized at each test depth the mean PO_2 ($\pm$ 1 standard deviation) will be reported. The maximum PO_2 observed during descent and the minimum PO_2 observed during ascent will be noted on the graph. Observations of alarm conditions for low PO_2, high $PO_{2,}$ and battery during the pre-dive and dive are to be recorded.

Performance requirement: Once stabilized at a test depth the controller must maintain +/- 0.05 ATM throughout the test period.

A.1.6 Carbon Dioxide Removal Canister Duration

The manufacturer, or the manufacturers' representative, will specify the CO_2 removal material to be used during this test. Carbon dioxide will be injected at 1.35 slpm. The breathing machine will simulate a ventilation rate of 40 slpm. The diluent gas will be air or nitrox, depending upon the CCR design. The data will be reported in tabular form as time to 0.5, 1.0, 2.0, and 5.0% Surface Equivalent Value (SEV) carbon dioxide (PCO_2), including mean +/- 1 SD. In addition, this data, % SEV PCO2 vs. time will be graphed representing the mean +/- 95 % confidence interval. Two canister runs for each candidate CCR will be performed at each test depth. If the results at a given depth vary by more than 20% of the lowest value a third test will be performed at that depth. The tests will be performed in water at a temperature of 40 +/- 1 F (3.9-5.0 C) and at depths of 60 fsw (18.3 msw), 100 fsw (30.5 msw), and 165 fsw (50.3 msw). Traditionally canister duration has been based on the time to reach 0.5% PCO_2 SEV, and this is still a valid criterion for dive planning purposes. A regression equation to 2.0% PCO_2 SEV, drawn from this test data, will allow the user to evaluate the consequences versus time of exceeding the estimated canister duration. This test is a representative test only and the results do not represent other combinations of water temperature, dive depth, and gas mixes. The Navy reported that the water temperature, dive depth, and background gas might affect canister performance. Therefore the manufacturer should be consulted for expected canister durations under conditions significantly different from the test conditions.

Performance requirements: Information only.

A.1.7 Battery Duration

Before unmanned control testing is begun a new battery conforming to the manufacturers' specification will be clearly marked with date/time and installed in the CCR. The battery will be used for O_2 control and other unmanned testing to verify battery life under operating conditions. Electronics run time will be derived from logged CCR operating time. Any battery anomalies will also be noted in the testing log.

Performance requirements: Information only for comparison with manufacturers estimated life. It is entirely possible that no batteries will fail during these tests. In that case the actual run time will still be useful information.

A.2 MANNED TESTING PERFORMANCE SPECIFICATIONS

The objective of manned tests is to verify unmanned test results for breathing resistance and oxygen control, and to obtain information on ease of use and diver comfort. CO_2 removal canister duration and battery life will be monitored but not necessarily taken to completion.

For reasons of safety, manned tests will be performed only after all unmanned tests have been satisfactorily completed.

Only NOAA approved test facilities will be acceptable for qualifying to this standard.
The manned test program is to concurrently evaluate breathing resistance, A.2.1, and measure oxygen control, A.2.2, during six dives of two divers each at depths of 60 fsw (18.3 msw) and 165 fsw (50.3 msw) using air as the diluent gas and one dive of two divers at a depth of 300 fsw (91.4 msw) using helium-oxygen, or nitrogen-helium-oxygen gases. A minimum of 5 divers with previous experience diving CCRs, and trained on the CCR being tested are to be used for this program.

A.2.1 Breathing Resistance

Using a dyspnea (shortness of breath) category rating scale (modified Borg or equivalent, 1 very slight, 2 slight, 3 moderate, 4 somewhat severe, 5 severe, 7 very severe, 10 maximal) each diver will evaluate the CCR's breathing performance for two progressive workloads at each depth using a bicycle ergometer. Note: This is a modification of Borg's Category Rating Scale of Perceived Exertion (CR-10) Borg (1982) Psychophysical basis of perceived exertion. Medicine and Science in Sports and Exercise, 14:377-381. Divers warm up during descent exercising at 25 watts. When they reach the test depth the workload is increased to 35 watts for three minutes, then 50 watts for three minutes, then 75 watts until the end of the bottom time, usually 3-5 minutes. During the third minute of each work level each diver uses hand signals to rate his level of breathing difficulty, and that assessment is recorded. During ascent the workload is decreased to 25 watts, and the diver continues to pedal at his own rate. At the end of the dive, including test diver familiarization and training dives, each diver completes an evaluation sheet for the preceding dive that includes: ease of donning, ease of strap adjustment for proper fit, ease of operating valves, ease of movement in the CCR, ease of doffing, and overall comfort.

Performance Standards: A mean-weighted average score of 3.0 (moderate or less) for breathing difficulty and a rating on the diver evaluation of adequate is considered acceptable.

A.2.2 Oxygen Control (Measured during the A.2.1 Breathing Resistance dives.)

A gas sampling port is located in the inhalation hose that provides a sampling rate of 500-800 mL/min. Inhalation levels for partial oxygen pressure (PO_2) and partial carbon dioxide levels (PCO_2) are measured at 1Hz and real time current value logged once every 30 seconds. Electronic data logging records the inspired 0_2 levels from which overshoot, time to stability, and control bandwidth are determined and graphically presented. The oxygen control of the CCR is determined by the mean PO_2 as ATM at steady-state conditions. The beginning and final PCO_2 levels are observed and recorded as percent surface equivalent value (%SEV).

Performance Standards: The CCR must maintain a PO_2 of $\pm$ 0.05 ATM in the stable condition.

A.2.3 REPORT

The testing laboratory will issue a report that includes: the testing procedures, the data from all of the tests, and a statement certifying which requirements of this standard the CCR met.